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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,774	07/13/2006	Mehmet Toner	022727-0138	3248
21125 7590 10/18/2007 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER KOSSON, ROSANNE	
			ART UNIT 1652	PAPER NUMBER
			NOTIFICATION DATE 10/18/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No.	Applicant(s)	
	10/563,774	TONER ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-45, drawn to a method for preserving a biomaterial/mammalian cell in which the transporter protein is a glucose transporter protein.

Group II, claim(s) 1-13, 15, 16, 19-26, 28, 29, 32-38, 40, and 43-45, drawn to a method for preserving a biomaterial/mammalian cell in which the transporter protein is a sucrose transporter protein.

Group III, claim(s) 1-13, 15, 16, 19-26, 28, 29, 32-38, 40, and 43-45, drawn to a method for preserving a biomaterial/mammalian cell in which the transporter protein is a mannose transporter protein.

Group IV, claim(s) 1-13, 15, 16, 19-26, 28, 29, 32-38, 40, and 43-45, drawn to a method for preserving a biomaterial/mammalian cell in which the transporter protein is a galactose transporter protein.

Group V, claim(s) 1-13, 15, 16, 19-26, 28, 29, 32-38, 40, and 43-45, drawn to a method for preserving a biomaterial/mammalian cell in which the transporter protein is a hexose transporter protein.

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Group VI, claim(s) 46-57, drawn to a mammalian cell prepared for preservation comprising a non-metabolizable carbohydrate and a glucose transporter protein.

Group VII, claim(s) 46, 47, 49 and 52-57, drawn to a mammalian cell prepared for preservation comprising a non-metabolizable carbohydrate and a sucrose transporter protein.

Group VIII, claim(s) 46, 47, 49 and 52-57, drawn to a mammalian cell prepared for preservation comprising a non-metabolizable carbohydrate and a mannose transporter protein.

Group IX, claim(s) 46, 47, 49 and 52-57, drawn to a mammalian cell prepared for preservation comprising a non-metabolizable carbohydrate and a galactose transporter protein.

Group X, claim(s) 46, 47, 49 and 52-57, drawn to a mammalian cell prepared for preservation comprising a non-metabolizable carbohydrate and a hexose transporter protein.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The requirement of unity of invention is not fulfilled because there is no technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Therefore, a technical relationship is lacking among the claimed inventions involving one or more special technical features.

The inventions of Groups I-X, do not share the common special technical feature of the set of three components that are a mammalian cell or biomaterial, a transporter molecule (transporter protein) and a preservation agent transported by the transporter molecule because Curtis (US 2003/0009024 A1) discloses human cells comprising a membrane transport protein designated 65484. This transport protein transports a variety of molecules, such as hexoses, disaccharides, hormones, peptides and neurotransmitters across the cell membrane, and this transport serves to preserve the cell by maintaining normal

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metabolism and health of the cell (see paragraphs 9, 71, 77, and 157). To preserve cells in which this transport protein is lacking or in which this transport mechanism is deficient, the gene for the transport protein may be cloned into a mammalian expression vector and expressed at the DNA and protein levels in mammalian cells (see paragraphs 206-215). As the human diet contains sugars and peptides, either ingested or as digestion products, and as humans consume pharmaceutical compositions, these compounds come in contact with the cell membranes.

Thus, the technical feature of a mammalian cell comprising the set of three components that are a mammalian cell or biomaterial, a transporter molecule (transporter protein) and a preservation agent transported by the transporter molecule does not define the invention over the prior art. Because the common special technical feature is not novel with respect to the cited reference, it is clear that the claims of Groups I-X lack a single common technical feature that defines them over the prior art.

Further, an international application containing claims to different categories of inventions will be considered to have unity of invention if the claims are drawn only to one of certain combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
 - (2) A product and process of use of said product; or
 - (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
 - (4) A process and an apparatus or means specifically designed for carrying out the said process; or
 - (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process (see 37 CFR 1.475(b)-(d)).
- In the instant case, the claims are drawn to multiple processes and a product, only a particular combination of which along with Group I may be considered for unity of invention, i.e., Group I and Group VI, (the first named process of using a product and the named product). Other groups are drawn to additional processes, and other combinations do not comply with the aforementioned Rules. Accordingly, a holding of lack of unity of invention is proper.

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This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows.

a) If one of Groups I-V is elected, in claim 2, Applicants must elect the species of one of the preservation methods listed. This election will be applied to claim 23.

b) If one of Groups I-V is elected, Applicants must elect the species of one of the storage methods, either storage in the dry state (claim 6) or storage in the frozen state (claim 7). This election will be applied to claims 35-36.

c) If one of Groups I-V is elected, in claim 10, Applicants must elect the species of one of the biomaterials listed. This election will be applied to claim 21.

If one of Groups VI-X is elected, in claim 56, Applicants must elect the species of one of the mammalian cells listed.

d) If one of Groups I-V is elected, in claim 16, Applicants must elect the species of one of the non-metabolizable carbohydrates listed. This election will be applied to claims 29 and 40.

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If one of Groups VI-X is elected, in claim 49, Applicants must elect the species of one of the non-metabolizable carbohydrates listed.

Applicants are required, in reply to this action, to elect a single species as indicated in a) - d) above to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 15, 19, 28, 39, 46 and 48.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1(f)(I)(B)(2), the species are not art-recognized equivalents.

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Each of the methods above uses different reagents and steps and has a different function and a different effect. Each of the biomaterials or cells above has a different structure, different biological, chemical and physical properties and a different function.

Because the claimed species are not art-recognized equivalents, a holding of lack of unity of invention is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction

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requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652



rk/2007-10-03

/Rebecca Prouty/
Primary Examiner
Art Unit 1652